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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,332	04/06/2007	David W. Morris	PP023362.0003	5041

27476 7590 06/17/2009

NOVARTIS VACCINES AND DIAGNOSTICS INC.
INTELLECTUAL PROPERTY- X100B
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EXAMINER	
HARRIS, ALANA M	

ART UNIT	PAPER NUMBER
1643	

MAIL DATE	DELIVERY MODE
06/17/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/573,332	MORRIS ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-55* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

1. Applicants are put on notice *this is not a species election.* With the election of Groups I-XVI Applicants are required to *further elect one sequence (unless denoted otherwise, i.e. claim 1, wherein two sequences are necessitated),* SEQ ID number or one human genomic sequence and its corresponding mRNA sequence from Tables 1-124. Moreover, if Applicants elect Group XVI Applicants must note the method implemented to identify the anti-cancer drug candidate.

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-3, drawn to a nucleic acid array for detecting a cancer associated (CA) nucleic acid.

Group II, claim(s) 4-8, drawn to a peptide array.

Group III, claim(s) 9-11, drawn to a compound that binds to a polypeptide of a peptide array.

Group IV, claim(s) 12-27, drawn to an isolated antibody or antigen binding fragment thereof, the hybridoma that produces the said antibody and a pharmaceutical composition comprising said antibody.

Group V, claim(s) 28 and 29, drawn to a kit for detecting cancer cells comprising an antibody.

Group VI, claim(s) 30, 42-44 and 49, drawn to a method for detecting CA protein (CAP) with an antibody.

Group VII, claim(s) 31 and 32, drawn to a method of administering an antibody.

Group VIII, claim(s) 33 and 34, drawn to a kit for diagnosing the presence of cancer comprising at least two polynucleotides.

Group IX, claim(s) 35 and 36, drawn to an electronic library comprising at least two CA polynucleotide sequences.

Group X, claim(s) 37, drawn to an electronic library comprising at least two CA polypeptide sequences.

Group XI, claim(s) 38-41, drawn to a method of screening for anticancer activity comprising providing a cell and contacting it with an anticancer drug.

Group XII, claim(s) 43 and 49, drawn to a method for detecting cancer associated with expression of a polypeptide comprising detecting the level of activity of at least one polypeptide.

Group XIII, claim(s) 45-48, drawn to a method for screening for a bioactive agent comprising determining the effect of said agent on the bioactivity of CAP.

Group XIV, claim(s) 50 and 51, drawn to a method for treating cancers comprising administering an inhibitor of a CAP.

Group XV, claim(s) 52-54, drawn to a method for inhibiting expression of CA gene comprising contacting said gene with a double stranded RNA comprising a sequence.

Group XVI, claim(s) 55, drawn to an anti-cancer drug candidate identified by a method.

3. The inventions listed as Groups I-XVI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

In the instant case, the methods and products rely upon polynucleotides, polypeptides and antibodies which differ in both structure and modes of action to such an extent and require non-coextensive searches to such an extent that they are considered to lack a substantial structural feature disclosed as being essential to the disclosed utility.

Furthermore, the special technical feature recited in claim 1, a nucleic acid array for detecting a CA nucleic acid comprising at least two nucleic acid probes comprising at least 10 contiguous nucleotides of a multitude of sequences is disclosed in Dai et al. / U.S. Patent number 7,171,311 B2 (filed January 15, 2003). Dai discloses two sequences, sequence 760 and sequence 1689 which are probes present on a microarray, see sequence alignment on following pages; column 8, lines 41-50; column 30; and column 42. Therefore, the technical feature recited in claim 1 is not special. Accordingly, the groups are not so linked as to form a single general concept under PCT Rule 13.1.

Sequence alignment between Applicants' SEQ ID NO: 21 and sequence 1689 from Patent 7171311

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US-10-342-887-1689
; Sequence 1689, Application US/10342887
; Patent No. 7171311
; GENERAL INFORMATION:
;  APPLICANT: Dai, Hongyue
;  APPLICANT:  He, Yudong
;  APPLICANT:  Linsley, Peter S.
;  APPLICANT:  Mao, Mao
;  APPLICANT:  Roberts, Christopher J.
;  APPLICANT:  Van 't Veer, Laura Johanna
;  APPLICANT:  Van de Vijver, Marc J.
;  APPLICANT:  Bernards, Rene
;  TITLE OF INVENTION: Diagnosis and Prognosis of Breast Cancer Patients
;  FILE REFERENCE: 9301-188-999
;  CURRENT APPLICATION NUMBER: US/10/342,887
;  CURRENT FILING DATE:  2003-01-15
;  PRIOR APPLICATION NUMBER: 60/298,918
;  PRIOR FILING DATE: 2001-06-18
;  PRIOR APPLICATION NUMBER: 60/380,710
;  PRIOR FILING DATE: 2002-05-14
;  PRIOR APPLICATION NUMBER: 10/172,118
;  PRIOR FILING DATE: 2002-06-14
;  NUMBER OF SEQ ID NOS: 2699
; SEQ ID NO 1689
;   LENGTH: 1487
;   TYPE: DNA
;   ORGANISM: Homo sapiens
US-10-342-887-1689

  Query Match             6.0%;  Score 500;  DB 5;  Length 1487;
  Best Local Similarity   91.7%;  Pred. No. 2.8e-90;
  Matches  561;  Conservative    0;  Mismatches    0;  Indels   51;  Gaps    1;

Qy       7748 TGTACTTTTATTTTACACAGAAACACTGCCTTTTTATTTATATGTACTGTTTTATCTGGC 7807
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          1 TGTACTTTTATTTTACACAGAAACACTGCCTTTTTATTTATATGTACTGTTTTATCTGGC 60

Qy       7808 CCCAGGTAGAAACTTTTATCTATTCTGAGAAAACAAGCAAGTTCTGAGAGCCAGGGTTTT 7867
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         61 CCCAGGTAGAAACTTTTATCTATTCTGAGAAAACAAGCAAGTTCTGAGAGCCAGGGTTTT 120

Qy       7868 CCTACGTAGGATGAAAAGATTCTTCTGTGTTTATAAAATATAAACAAAGATTCATGATTT 7927
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        121 CCTACGTAGGATGAAAAGATTCTTCTGTGTTTATAAAATATAAACAAAGATTCATGATTT 180

Qy       7928 ATAAATGCCATTTATTTATTGATTCCTTTTTTCAAAATCCAAAAAGAAATGATGTTGGAG 7987
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        181 ATAAATGCCATTTATTTATTGATTCCTTTTTTCAAAATCCAAAAAGAAATGATGTTGGAG 240

Qy       7988 AAGGGAAGTTGAACGAGCATAGTCCAAAAAGCTCCTGGGGCGTCCAGGCCGCGCCCTTTC 8047
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        241 AAGGGAAGTTGAACGAGCATAGTCCAAAAAGCTCCTGGGGCGTCCAGGCCGCGCCCTTTC 300

Qy       8048 CCCGACGCCCACCCAACCCCAAGCCAGCCCGGCCGCTCCACCAGCATCACCTGCCTGTTA 8107
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        301 CCCGACGCCCACCCAACCCCAAGCCAGCCCGGCCGCTCCACCAGCATCACCTGCCTGTTA 360

Qy       8108 GGAGAAGCTGCATCCAGAGGCAAACGGAGGCAAAGCTGGCTCACCTTCCGCACGCGGATT 8167
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        361 GGAGAAGCTGCATCCAGAGGCAAACGGAGGCAAAGCTGGCTCACCTTCCGCACGCGGATT 420

Qy       8168 AATTTGCATCTGAAATAGGAAACAAGTGAAAGCATATGGGTTAGATGTTGCCATGTGTTT 8227
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        421 AATTTGCATCTGAAATAGGAAACAAGTGAAAGCATATGGGTTAGATGTTGCCATGTGTTT 480

Qy       8228 TAGATGGTT---------------------------------------------------- 8236
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              ||||||||
Db         481 TAGATGGTTTCTTGCAAGCATGCTTGTGAAAATGTGTTCTCGGAGTGTGTATGCCAAGAG 540

Qy        8237 TGCACCCATGGTACCAATCATGAATCTTTGTTTCAGGTTCAGTATTATGTAGTTGTTCGT 8296
               ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         541 TGCACCCATGGTACCAATCATGAATCTTTGTTTCAGGTTCAGTATTATGTAGTTGTTCGT 600

Qy        8297 TGGTTATACAAG 8308
               ||||||||||||
Db         601 TGGTTATACAAG 612
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Sequence alignment between Applicants' SEQ ID NO: 53 and sequence 760 from Patent 7171311

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US-10-342-887-760
; Sequence 760, Application US/10342887
; Patent No. 7171311
; GENERAL INFORMATION:
;  APPLICANT: Dai, Hongyue
;  APPLICANT:  He, Yudong
;  APPLICANT:  Linsley, Peter S.
;  APPLICANT:  Mao, Mao
;  APPLICANT:  Roberts, Christopher J.
;  APPLICANT:  Van 't Veer, Laura Johanna
;  APPLICANT:  Van de Vijver, Marc J.
;  APPLICANT:  Bernards, Rene
;  TITLE OF INVENTION: Diagnosis and Prognosis of Breast Cancer Patients
;  FILE REFERENCE: 9301-188-999
;  CURRENT APPLICATION NUMBER: US/10/342,887
;  CURRENT FILING DATE:  2003-01-15
;  PRIOR APPLICATION NUMBER: 60/298,918
;  PRIOR FILING DATE: 2001-06-18
;  PRIOR APPLICATION NUMBER: 60/380,710
;  PRIOR FILING DATE: 2002-05-14
;  PRIOR APPLICATION NUMBER: 10/172,118
;  PRIOR FILING DATE: 2002-06-14
;  NUMBER OF SEQ ID NOS: 2699
; SEQ ID NO 760
;   LENGTH: 1145
;   TYPE: DNA
;   ORGANISM: Homo sapiens
US-10-342-887-760

  Query Match             50.1%;  Score 305.4;  DB 5;  Length 1145;
  Best Local Similarity   99.7%;  Pred. No. 8.2e-75;
  Matches  306;  Conservative    0;  Mismatches    1;  Indels    0;  Gaps    0;

Qy          95 AGCAGGACAGGCTGCTTTGGTTTGTGACCTCCAGGCAGGACGGCCATCCTCTCCAGAATG 154
               ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          79 AGCAGGACAGGCTGCTTTGGTTTGTGACCTCCAGGCAGGACGGCCATCCTCTCCAGAATG 138

Qy         155 AAGATCTTCTTGCCAGTGCTGCTGGCTGCCCTTCTGGGTGTGGAGCGAGCCAGCTCGCTG 214
               ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         139 AAGATCTTCTTGCCAGTGCTGCTGGCTGCCCTTCTGGGTGTGGAGCGAGCCAGCTCGCTG 198

Qy         215 ATGTGCTTCTCCTGCTTGAACCAGAAGAGCAATCTGTACTGCCTGAAGCCGACCATCTGC 274
               ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         199 ATGTGCTTCTCCTGCTTGAACCAGAAGAGCAATCTGTACTGCCTGAAGCCGACCATCTGC 258

Qy         275 TCCGACCAGGACAACTACTGCGTGACTGTGTCTGCTAGTGCCGGCATTGGGAATCTCGTG 334
               ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         259 TCCGACCAGGACAACTACTGCGTGACTGTGTCTGCTAGTGCCGGCATTGGGAATCTCGTG 318

Qy         335 ACATTTGGCCACAGCCTGAGCAAGACCTGTTCCCCGGCCTGCCCCATCCCAGAAGGCGTC 394
               ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         319 ACATTTGGCCACAGCCTGAGCAAGACCTGTTCCCCGGCCTGCCCCATCCCAGAAGGCGTC 378
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Qy        395 AATGTGG 401
              ||||| |
Db        379 AATGTTG 385
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5. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

a. tumor suppressor,

b. low density lipoprotein receptor,

c. G protein coupled receptor,

d. apoptosis inhibitor,

e. ion transport,

f. calcium binding,

g. cell adhesion,

h. signalling,

i. protein kinase receptor, and

j. signal transduction.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

A bioactive agent is capable of modulating activities.

The following claim(s) are generic: 47.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the modes of activity differ in cellular events and components that trigger the different activities.

6. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during

prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

9. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached Monday through Saturday, 7:30 am to 6:30 pm with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alana M. Harris, Ph.D.
29 May 2009
/Alana M. Harris, Ph.D./
Primary Examiner, Art Unit 1643